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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,202	04/13/2006	Osamu Honmou	033873-0108	4131

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,202	HONMOU ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8,9,11-15 and 17-30* is/are pending in the application.

4a) Of the above claim(s) *20-22,25 and 27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8,9,11-15,17-19,23,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/2010; 6/21/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 19 July 2010.

Claim Status

Claims 6, 8, 9, 11-15 and 17-30 are pending. Claims 1-5, 7, 10, 16 are cancelled. Claims 6, 9, 18, 19 and 23 are amended. However, claims 20-22, 25 and 27-30 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 are under current examination.

Priority

This application claims benefit as a 371 National Stage application of PCT/JP04/09386 (filed 06/25/2004). The application also claims benefit from foreign application, JAPAN 2003-432329 (filed 12/26/2003). Accordingly, the instant application has been granted the benefit date, 26 June 2003, from foreign application, JAPAN 2003-432329.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 15 April 2010 and 21 June 2010 consisting of 2 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

RESPONSE TO ARGUMENTS

35 USC § 103

Mahmood

The rejection of claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 under 35 U.S.C. 103(a) as being unpatentable over Mahmood et al. (Neurosurgery, Vol.49, No.5, November 2001: 1196-1204) in view of Chen et al. (Neuropharmacology. 2000; 39: 711-716) is withdrawn in response to the applicants arguments and/or claim amendments.

The applicant's claim amendments have been fully considered and are persuasive. The applicant has amended the claims so that the mesenchymal stem cells are co-transfected with hTERT and at least one of: BDNF gene, PLGF gene, GDNF gene, or IL-2 gene. Neither Mahmood et al. nor Chen et al. teach or suggests the co-transfection of hTERT and one of the cytokines recited in the instant claims.

Therefore, the examiner hereby withdraws the rejection of claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 under 35 U.S.C. 103(a) as being unpatentable over Mahmood et al. in view of Chen et al.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION

Claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

The amended claims are directed to treatment methods that utilize a mesenchymal stem cell having both (1) a vector comprising an hTERT gene and (2) a vector having at least one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene. The examiner has been unable to find description of such a genetically modified cell in the instant specification or the originally filed claims. Additionally, the specification does not seem to provide examples of the claimed methods, using a genetically engineered mesenchymal stem cell having both (1) a vector comprising an hTERT gene and (2) a vector having at least one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene. The applicant did not provide citations in the Remarks, filed 7/19/2010, to support the

assertion that no new matter was introduced with the claim amendments of that date. Accordingly, the examiner concludes that the claim amendments of 7/19/2010 have improperly introduced new matter.

LACK OF ENABLEMENT

Claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the

breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

The structure of the genetically engineered mesenchymal stem cells, being critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The specification has enabled a method of treating neurological disease using a mesenchymal stem cell comprising a vector comprising an hTERT gene. The specification has enabled a method of treating neurological disease using a mesenchymal stem cell comprising a vector comprising having at least one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene. However, the specification has not enabled a method of treating neurological disease using a mesenchymal stem cell having both (1) a vector comprising an hTERT gene and (2) a vector comprising at least one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene.

Likewise, the specification has enabled (1) a mesenchymal stem cell comprising a vector comprising an hTERT gene; and (2) a mesenchymal stem cell comprising a vector comprising having at least one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene. However, the specification has not enabled a mesenchymal stem cell having both (1) a vector comprising an hTERT gene and (2) a vector comprising at least one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene.

At the time of filing, the art is silent as to providing a mesenchymal stem cell having both (1) a vector comprising an hTERT gene and (2) a vector comprising at least

one of BDNF gene, PLGF gene, GDNF gene, or IL-2 gene. Furthermore, at the time of filing, the art is silent regarding using such a cell for treating neurological disease.

Accordingly, given the breadth of the claims and the limited scope of the specification and state of the art, an undue quantity of experimentation is require to make and use the invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SCOTT LONG/
Primary Examiner, Art Unit 1633